Maintaining Activity and Nutrition through Technology-Assisted Innovation in Primary Care (MAINTAIN-pc)

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Abstract

Objective: To evaluate benefit of coaching in an electronic health record (EHR)-based weight maintenance intervention.

Scope:
Background: Weight regain after intentional loss is common.
Context: Few studies have addressed this aspect of the obesity epidemic.
Settings: 10 primary care practices in Pittsburgh, PA.
Participants: Outpatients adults (BMI ≥ 25 kg/m²) with intentional 5% weight loss in past 2 years, and no bariatric procedures in past 5 years.

Methods:
Study Design: Randomized clinical trial randomized 1:1 to tracking tools with or without coaching conducted from 2012-2017. Outcome assessors were unblinded.
Interventions: Study enrolled 194 unblinded participants (98 coaching; 96 tracking). EHR tools for both groups included flowsheets for tracking weight, diet, and physical activity (PA); standardized surveys; and reminders. Coaching participants received 24 months of personalized coaching through EHR patient portal.
Measures: Primary outcome of this trial was weight change at 24-months. Secondary outcomes included 5% weight loss maintenance, changes in BMI, waist circumference, steps, health related quality of life, function, blood pressure, and satisfaction.
Limitations: Results may not generalize to other settings or populations. Unblinded study staff. Duration was limited to 24 months (36 months planned). Missing data due to missed follow ups. Analyses of secondary and post-hoc variables are only exploratory.

Results:
Principal Findings: Weight regain in coaching group compared with other EHR-based care was a median of 1.4 kg vs 4.5 kg after 24 months, a difference that was statistically significant.

Other Outcomes: At 24 months, 65% in coaching group had maintained 5% weight loss, compared to 49% in other care.

Key words: weight maintenance, weight management, EHR tools, lifestyle, obesity

Words: 250/250
Final Report

2. **Purpose**
This randomized clinical trial was designed and conducted to test the hypothesis that there would be an incremental benefit of personalized coaching and PCP support in an EHR-based intervention designed to help primary care patients successfully maintain recent intentional weight loss of ≥ 5%.

3. **Scope**

**Background and Context**
Obesity is associated with numerous chronic medical conditions.1, 2 Most individuals who lose weight through lifestyle interventions (i.e., diet and physical activity) eventually regain.3 Sustained lifestyle support1, 4-6 and consistent self-monitoring of behaviors and weight7, 8 are key strategies for promoting successful maintenance of weight loss. Thus, interventions that support self-monitoring by leveraging the long-term relationship that patients share with their primary care health team could address this problem.

Few randomized clinical trials to date have focused on weight maintenance and most did not recruit patients with multiple weight-related co-morbidities.9-11 Others that recruited from primary care did not coordinate the intervention with routine care and the ongoing patient-provider relationship.12, 13 Using the electronic health record (EHR), weight maintenance interventions can be integrated into routine primary care to identify potentially eligible patients, establish ongoing contact with patients during the intervention, and engage the primary care provider (PCP). EHR adoption by ambulatory physicians has more than doubled from 42% in 2008 to nearly 87% in 2015. 14, 15

**Settings:** We focused on primary care practice-based recruitment. Practice-based recruitment tools in 9 primary care practices and 1 specialty practice (Endocrinology) included: (a) EHR alert identifying potentially eligible patients with related referral order to study, (b) visits to practice meetings to familiarize physicians and staff with this trial, and (c) flyers and brochures. Secondary (non-practice-based) recruitment efforts included letters to research registry participants, postings in an electronic campus newsletter, and outreach to local weight loss studies. Eligibility was verified based on weight loss of ≥5% in the EHR.

**Participants:** Participants were recruited between October 2013 and February 2015. Follow up was completed by February 2017. Eligibility criteria included age between 18 to 75 years, intentional weight loss of ≥5% in the past 2 years, access to an Internet-connected computer, and a UPMC PCP. Exclusion criteria included a medical explanation for recent weight loss (e.g., malignancy), active preparation for bariatric surgery, bariatric surgery in the past 5 years, or pregnancy.
4. Methods

Study Design
Maintaining Activity and Nutrition through Technology-Assisted Innovation in Primary Care (MAINTAIN-pc) was a randomized clinical trial conducted in coordination with primary care sites affiliated with the University of Pittsburgh Medical Center (UPMC).

This trial was initially designed to be a 36-month intervention, with primary outcome determined by weight change at the end of intervention. This was specified in the grant application (submitted September 22, 2010; resubmitted January 12, 2012), the initial IRB application (approved April 25, 2013), and trial registration (September 6, 2013). Due to delays in EHR build and recruitment, we determined that we could not deliver a 36-month intervention to all participants and truncated the intervention to 24 months; 24 month weight change was the revised primary outcome. We made this decision while data collection was ongoing and before any data analysis. We notified our funder of the change, and updated IRB protocol (with revised consent); the IRB approved our revised protocol on September 25, 2015.

Randomization
After telephone screening, baseline assessment, and approval by PCP, eligible participants were assigned 1:1 to coaching or tracking groups using computer-generated permuted block randomization with block sizes of four and six individuals and stratified by sex and site of primary care. The study statistician (DT) generated the allocation sequence; assignments were given to participants after baseline assessment and before orientation by study staff after staff obtained assignment from data center website.

Data sources/Collections:

Interventions:
All participants received 1-hour orientation to the EHR-based tracking tools, plus basic information about healthy eating and safe physical activity. Participants in the coaching group received an additional 10-minute introduction to the role of the coaches. Both the coaching and tracking groups received weekly reminders to enter information into the EHR-based tracking tools; all participants were encouraged to log in daily and enter current weight, dietary and physical activity data. Participants randomized to the coaching group received 2 years of personalized health coaching through the EHR patient portal.

Coaches contacted coaching participants weekly exclusively via the EHR for one month, biweekly for months 2-5, monthly for months 6-12, and quarterly for months 13-24. They sent participants brief questionnaires on topics relevant to weight management; questionnaires included a free text field where participants could ask questions or note barriers they were facing. Based on participant responses and self-monitoring data in the EHR flowsheets, the coaches wrote a brief personalized note to each participant with advice...
about the topic of the questionnaire as well as responses to any queries or barriers mentioned by the participant. Coaching participants who did not answer questionnaires or log information into the flowsheet for 2-weeks were considered inactive and contacted by phone or e-mail. Inactive participants were invited to reengage at any time. Coaching participants were also able to send secure messages to the health coach and received responses within 2 business days. In contrast, tracking participants received questionnaires related to general health promotion (e.g., vaccines) each quarter but received no feedback to questionnaire responses or flowsheet entries.

Referring PCPs of coaching group received regular support, including real-time progress reports with counseling tips delivered via EHR, notification of weight change of ≥ 10-pound increments from enrollment weight, and annual progress reports at 12 and 24 months. The progress reports were developed using feedback from PCPs and consisted of a single page summary of participant weight (current, trajectory, goal), status in program (active/inactive), use of MAINTAIN flowsheets (with data if recently used), and brief subjective comments from participant’s coach. Reports were delivered to the PCP via EHR 24-48 hours preceding a scheduled office visit with an electronic copy simultaneously sent to the participant. Referring PCPs of tracking group received annual progress reports at 12 and 24 months. More information about the development of intervention and coaching protocol has been previously published.16

**Measures:**
Measures were taken at 0, 6, 12, and 24 months with $25 compensation for each assessment. Study assessment staff were not blinded to treatment group given the small (n=2) number of staff working on the project at a given time and the objectively measured primary outcome (weight) using a digital scale. Staff measuring weights did not provide coaching or attend meetings where participant progress was discussed.

Weight was measured in pounds using a calibrated Tanita WB-100A scale with the participant in light clothing and no shoes. Other weight outcomes included percent with 5% weight maintenance and changes in body mass index (BMI). Height was measured in inches using a standard portable stadiometer (Charder HM 200P) and BMI calculated as kg/m².

Waist circumference was measured with a Gulick flexible tape measure.

Physical activity was assessed with Omron pedometers (HJ-720ITC), which participants wore for 14 days during waking hours after receiving the pedometer at the in-person assessment and returning it using a pre-paid mailer. Pedometer days with at least 500 steps were valid and the mean calculated from valid days.

Health-related quality of life (HRQOL) was measured using the SF-36 17and both physical (PCS) and mental (MCS) composite scores were calculated. Impact of Weight on Quality of Life-Lite (IWQOL-Lite)18 and utility data were also collected, but not reported here.
Physical function was measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)\textsuperscript{19}.

Blood pressure using an Omron BP710 automated arm blood pressure monitor.

Participant satisfaction was measured using a modified version of the Telemedicine Satisfaction and Usefulness Questionnaire (TSUQ)\textsuperscript{20}. PCP satisfaction was also measured, but not reported here.

Diet and adherence to EHR tracking (proxy for adherence to intervention) were included as post hoc exploratory outcomes, as these measures are usually included in weight trials as explanatory variables. Weekly EHR reports showed participant-entered tracking data from EHR flowsheets in the past week. Diet was assessed using the Connor Diet Habit Survey\textsuperscript{21}.

Demographic characteristics and medical co-morbidities were assessed using self-report questionnaires. Participants self-identified race at baseline using fixed categories based on those used by NIH.

Participants were asked about any adverse medical events that might have affected their participation in usual daily activities at each follow-up assessment and self-rated the severity of the event (as opposed to a formal adjudication process).

The assessment window for collecting participant data was three months (i.e., six weeks before/after the “target” visit date). If a participant missed an assessment visit, a clinic-collected weight in the identical assessment window from the HER was obtained, if available.

\textit{Limitations:}
This study has several limitations. First, although this trial included a variety of practice types and limited inclusion and exclusion criteria, this is still a single-site trial, limiting generalizability. Second, the final sample had 26\% men and 12\% non-white participants. This proportion of male participants is consistent with other weight management interventions and proportion of non-white participants reflective of Allegheny County. Third, the fact that study staff were not blinded possibly introducing some bias in outcome assessment, which was partially ameliorated by the fact that the primary outcome (weight) was objectively assessed. Fourth, while the amount of missing data at 24 months was similar to other weight management studies of this duration and fairly equal between groups, it does introduce a potential bias which was only partially addressed by the analyses performed to more conclusively characterize the nature of the missing data. Fifth, since we did not adjust p-values for multiple comparisons, analyses of secondary and post-hoc variables should be considered exploratory.
5. Results:

**Principal Findings:** Among 194 participants who were randomized (mean age 53.4 (SD 12.2); 143 (74%) women), 171 (88%) completed this trial. Mean weight and BMI at baseline were 85.8 (SD 19.1) kg and 30.4 (5.9) kg/m². Participants lost a mean body weight of 11.3% (SD 6.6) before enrolling. At 24 months, median weight regain was 1.4 kg in coaching and 4.5 kg in tracking. The median weights for participants in coaching and TO groups at each follow up assessment are shown in Figure 1 and individual results from baseline to 24 months in Figure 2. Compared to the tracking participants, coaching participants had regained less weight at each follow-up assessment (Table 1). In linear mixed models, there was a significant difference in weight change between groups at 24 months with a difference of -2.86 kg, 95% CI (-4.61, -1.12). Similar results were observed when the models were adjusted for sex, clinic type, as hypertension and baseline weight, with difference between groups of -2.94 kg, 95% CI (-4.65, -1.23) at 24 months. Results were also similar when percent of intentional weight loss (-2.87 kg, 95% CI (-4.62, -1.13)) or amount of intentional weight loss (-2.88 kg, 95% CI (-4.61, -1.12)) before randomization were in final model rather than baseline weight. Corresponding to the differences in weight outcomes, there were also significant differences in percent weight loss and BMI changes between coaching and tracking groups (Table 1) at 24 months.

![Figure 1](image1.png)  
Figure 1. Minimum, first quartile, median, third quartile, and maximum quartile weights over 24 months (N=194)

![Figure 2](image2.png)  
Figure 2. Individual change in weight (kg) baseline to 24 months

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Change in weight outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td><strong>Primary Outcome</strong></td>
<td></td>
</tr>
<tr>
<td>Weight change from baseline, median (IQR), kg, [No.]</td>
<td></td>
</tr>
<tr>
<td>Coaching group</td>
<td>95.7 (27.2) [96]</td>
</tr>
<tr>
<td>Tracking group</td>
<td>78.7 (24.9) [96]</td>
</tr>
<tr>
<td>P value</td>
<td>0.0256</td>
</tr>
<tr>
<td>Weight change from baseline, median (IQR), %, [No.]</td>
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</tr>
<tr>
<td>Coaching group</td>
<td>--</td>
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<tr>
<td>Tracking group</td>
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<tr>
<td>P value</td>
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</tbody>
</table>
Other Outcomes:
Secondary Outcomes
At 24 months, 65% in coaching and 49% in tracking still demonstrated weight loss of at least 5%. There were no differences, however, between groups in waist circumference changes, pedometer step changes, HRQOL (PCS/MCS), WOMAC score, systolic or diastolic BP.

At 24 months, coaching group participants had a higher degree of satisfaction with the program than those in tracking group, as measured by the modified TSUQ (mean 3.4 (SD 0.7) vs. 3.1 (0.6); p=0.01), although satisfaction was in moderate range in both groups.

Post hoc Outcomes and Adverse Events
There were no significant differences in changes in dietary scores between groups at 24 months. Metrics related to use of the EHR flowsheets were a proxy for adherence (Table 2). Instances of MAINTAIN flowsheet use were greater in the coaching group for all measures at all times, but attenuated in both groups over time. For example, participants in the coaching group entered a weight 25.0 times (about 8 times per month) in months 4-6 of the study, whereas tracking participants did so 17.2 times (about 6 times per month) over the same time period; by months 22-24, weight entry had decreased to 11.7 times (about 4 times per month) in coaching group and 9.5 (about 2 times per month) in the tracking group.

Participants self-reported 115 adverse events (48 in coaching; 67 in tracking) and 30 serious events (10 in coaching; 20 in tracking) over the 24-month trial. “Serious events” (e.g., surgery) were defined by participants as those that caused the participant to substantially alter his/her routine (i.e., unable to carry out normal activities). None of the serious events were related to the intervention.

Table 2. Participant adherence in MAINTAIN-pc as measured by use of tracking tools

<table>
<thead>
<tr>
<th>Flowsheet Summary Entry (total instances), mean (SD)</th>
<th>Months 4-6</th>
<th>Months 10-12</th>
<th>Months 22-24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coaching Group (N=95)</td>
<td>36.1 (43.2)</td>
<td>24.3 (35.1)</td>
<td>18.5 (35.6)</td>
</tr>
<tr>
<td>Tracking Group (N=93)</td>
<td>27.4 (36.6)</td>
<td>19.4 (32.6)</td>
<td>15.4 (37.1)</td>
</tr>
<tr>
<td>Weight Entry (instances), mean (SD)</td>
<td>25.0 (33.9)</td>
<td>17.4 (33.2)</td>
<td>13.1 (31.8)</td>
</tr>
<tr>
<td>Coaching Group (N=95)</td>
<td>24.1 (35.7)</td>
<td>18.6 (32.4)</td>
<td>17.3 (35.1)</td>
</tr>
<tr>
<td>Tracking Group (N=93)</td>
<td>17.2 (28.0)</td>
<td>9.6 (25.4)</td>
<td>6.0 (22.4)</td>
</tr>
<tr>
<td>Diet Tracking Behavior – Calorie or Fat (instances), mean (SD)</td>
<td>30.4 (37.6)</td>
<td>22.0 (34.3)</td>
<td>17.3 (35.1)</td>
</tr>
<tr>
<td>Coaching Group (N=95)</td>
<td>24.5 (35.5)</td>
<td>17.4 (32.5)</td>
<td>11.9 (28.8)</td>
</tr>
<tr>
<td>Tracking Group (N=93)</td>
<td>22.0 (34.3)</td>
<td>17.4 (32.5)</td>
<td>11.9 (28.8)</td>
</tr>
</tbody>
</table>

Discussion
In this trial, the incremental addition of coaching and PCP feedback to EHR-based tracking tools was more effective than EHR-based tracking tools alone in supporting desired weight outcomes at 24 months in a group of primary care patients with prior intentional weight loss. There were no significant differences in other secondary outcomes between groups over the same time period.

Unlike weight loss trials, there are relatively few weight maintenance trials with which to
compare this trial’s results. A previous trial compared three conditions (in-person intervention, Internet-based intervention, control) in maintenance of weight loss over an 18-month period after loss.\textsuperscript{11} Compared to the our study, participants in this earlier trial had greater weight loss before enrollment (10% loss was required to enter study) and in-person intervention was shown to be most effective for weight maintenance with mean weight regain of 2.5 kg (compared to 4.5 kg Internet-based and 4.7 kg control) at 18 months. The results for coaching group participants at 24 months were more comparable to those in the prior trial’s in-person intervention. Unlike the prior trial’s Internet-based intervention, our trial’s coaching group was not augmented by in-person sessions other than orientation.

Another maintenance trial that used an Internet-based intervention\textsuperscript{9} demonstrated an in-person intervention was superior to both Internet-based and self-directed interventions at 30 months, but the Internet-based approach appeared superior to self-directed at intermediate time-points of 18 and 24 months. The attrition of the effect in the Internet-based group may have been partially due to diminished use of the Internet-based tools, a phenomenon also observed in this trial. More recently, a study of the effect of a telephone-based weight maintenance intervention in a group of veterans who had lost weight in phase one of an RCT and observed lesser regain at 56 weeks in the intervention compared to control group (0.75 vs 2.36 kg), effect sizes comparable to this trial’s 12 month\textsuperscript{13} results.

While overall this trial’s results are comparable to the previous literature, none of the previous trials incorporated use of the EHR to communicate with participants or PCPs. This trial’s EHR-based delivery is notable as it facilitates real-time clinical updates coordinated with routine care. The EHR that was leveraged is commonly used in primary care and could be adapted for weight maintenance counseling without excessive cost or programming requirements. In a systematic review of EHR-based weight interventions, Baer and colleagues concluded that relatively few studies have examined EHR-based tools to help clinicians address weight.\textsuperscript{22} Moreover, studies usually focus on identification of overweight/obesity rather than tools to help patients or physicians actively manage weight.

The superior weight outcomes in the coaching group were likely due to the coaching that this group received. Online coaching –particularly aspects related to encouragement and responsiveness to questions\textsuperscript{23} - has been valued by patients seeking weight management support in primary care settings. Weight outcomes may also have been affected by differential use of the tracking tools in the EHR and the additional reinforcement provided to the referring PCPs of the participants in this group. There was no significant difference in secondary outcomes, such as PA measures, possibly due to the way these outcomes were measured or the fact that the study was not powered to detect differences in these outcomes.

The use of tracking tools decreased in both groups over time. This may reflect decreased novelty, or the fact that new technologies for tracking are continuously being developed and released. Technical issues sometimes inhibited the use of EHR tools, particularly system-wide flowsheet redesign late in the intervention that made data entry more burdensome. Despite
these occasional problems, this trial was a successful deployment of a full-scale lifestyle intervention using standard EHR tools.

This trial demonstrates numerous strengths. To our knowledge, this is the first clinical trial to evaluate a lifestyle intervention completely embedded in the EHR. This trial capitalized on the ability of the EHR to communicate with both PCPs and patients and to document all patient progress at every assessment point along with routine health care data. The referral and follow-up process for this trial mirrored those for other clinical services. This trial used a collaborative model of working with IT in developing the EHR-based tools and PCPs in developing feedback reports. Both of these collaborations increase the likelihood that this trial protocol could be implemented in other routine care settings and perhaps streamlined with new EHR functionality.

Conclusion
Among adults with at least 5% intentional weight loss, use of EHR-based coaching compared with other EHR-based care resulted in less weight regain. Further research is needed to assess longer-term effectiveness, generalizability, and cost-effectiveness.

Significance: MAINTAIN-pc demonstrated that the EHR can be used as an effective venue for delivering coaching to patients with recent intentional weight loss. This is important since many people regain weight after intentional loss.

Implications: Since the EHR is readily available in many clinical sites, MAINTAIN-pc could be readily disseminated if appropriate staff are identified to coach patients.

6. List of Publications and Products

Abstracts and Poster Presentations

Eng M, McTigue KM, Simkin-Silverman LR, Huber KA, Funair L, Conroy MB. Primary Care Provider Feedback for Improving Clinical Progress Reports on Weight Maintenance [abstract]. Society of General Internal Medicine annual meeting in San Diego, CA, April 2016. Accepted poster presentation.


Conroy MB, McTigue KM, Bryce CL, Huber K, Simkin-Silverman LR, Tudorascu D, Comer D,
Hess R, Fischer GS. Promoting Weight Maintenance with Electronic Health Record Tools in a Primary Care Setting: Baseline results from the MAINTAIN-pc trial. Obesity Society annual meeting in Los Angeles, CA, Nov 2015. Accepted poster presentation.


Barone Gibbs B, Tudorascu D, Bryce C, Comer D, Fischer GS, Hess R, Huber KA, McTigue KM,

Molly B. Conroy, MD, MPH; Kathleen M. McTigue, MD, MS, MPH; Cindy L. Bryce, PhD; Dana Tudorascu, PhD; Bethany Barone Gibbs, PhD; Jonathan Arnold, MD, MSE; Diane Comer, MS; Rachel Hess, MD, MS; Kimberly Huber, MPH; Laurey R. Simkin-Silverman, PhD; Gary S. Fischer, MD. Promoting weight maintenance through electronic health record-based coaching in a primary care setting: 24-month results from the MAINTAIN-pc trial. Society of General Internal Medicine annual meeting in Denver, CO, April, 2018. Oral presentation


Manuscripts


References


